Supreme Court, U.S.
FILED
JUL 26 2015
OFFICE OF THE CLERK

No. 14-1538

IN THE

Supreme Court of the United States

LIFE TECHNOLOGIES CORPORATION; INVITROGEN IP HOLDINGS, INC.; APPLIED BIOSYSTEMS, LLC,

Petitioners,

v.

PROMEGA CORPORATION,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* AGILENT TECHNOLOGIES, INC. IN SUPPORT OF PETITIONERS

Bradford Paul Schmidt
AGILENT TECHNOLOGIES, INC.
5301 Stevens Creek Boulevard
Santa Clara, California 95051

John M. Griem, Jr.*
Judith M. Wallace
CARTER LEDYARD
& MILBURN LLP
2 Wall Street
New York, New York 10005
212-732-3200
griem@clm.com

Counsel for Amicus Curiae
Agilent Technologies, Inc.

* *Counsel of Record*

July 28, 2015

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

INTEREST OF AMICUS CURIAE 1

SUMMARY OF ARGUMENT 3

ARGUMENT 5

I. COMPLEX GLOBAL MANUFACTURING OPERATIONS AND SOPHISTICATED SUPPLY CHAIN MANAGEMENT SYSTEMS ARE THE NORM TODAY 5

A. Origins and Evolution of Supply Chain Management Systems 6

B. Modern Supply Chain Management Requires Agile, Resilient, Efficient Systems for Supplying Products and Components Worldwide 8

C. Agilent's Supply Chain Management Illustrates the Challenges Faced by Multinational Manufacturers 9

II. AGILENT'S ESTROGEN/PROGESTERONE RECEPTIVITY TEST KITS FOR BREAST CANCER DIAGNOSIS ILLUSTRATE THE POTENTIAL UNDUE CONSEQUENCES OF THE FEDERAL CIRCUIT'S RULING 12

A. Estrogen/Progesterone Receptor Test Kits for Breast Cancer Diagnosis Illustrate the Use of Commonplace Components 12

B. The Federal Circuit's Interpretation Could Render the Manufacturing and Use of Common, Interchangeable Components in Tests Kits Such as the Estrogen/Progesterone Receptor Kits Unduly Complex 15

III. THE FEDERAL CIRCUIT'S DECISION INCREASES THE RISK AND COST OF U.S. MANUFACTURING OF COMPONENTS AND THEREBY DISCOURAGES U.S. MANUFACTURING 16

CONCLUSION 18

TABLE OF AUTHORITIES

Cases:

Ass'n for Molecular Pathology v. Myriad Genetics, Inc.,133 S. Ct. 2107 (2013) 15

Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972) 7, 16

Promega Corp. v. Life Technologies Corp., 773 F.3d 1338 (Fed. Cir. 2014) 1, 4

Statutes and regulations:

35 U.S.C. 271(f) 4, 5, 6, 16

Miscellaneous:

1984 U.S. Code Cong. & Admin. News, p. 5827, *Section-By-Section Analysis of H.R. 6286, Patent Law Amendments Act of 1984*, 130 Cong. Rec. H 10525 (Oct. 1, 1984). 16

Agilent Technologies, Inc., Agilent Fact Sheet (Mar. 18, 2015), http://www.agilent.com/about/companyinfo/agilent-fact-sheet.pdf 1, 2

Agilent Technologies, Inc., Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 (Dec. 22, 2014), Sec. & Exch. Comm'n File No. 001-15405..... 1, 2, 3, 10, 13

Miscellaneous—Continued:

Agilent Technologies, Inc., Company Information, http://www.agilent.com/about/-companyinfo/index.html 2

American Society of Clinical Oncology, *Estrogen and Progesterone Receptor Testing for Breast Cancer*, http://www.cancer.net/research-and-advocacy/asco-care-and-treatment-recommendations-patients/estrogen-and-progesterone-receptor-testing-breast-cancer..... 12

Sunil Chopra and Manhohan S. Sodhi, *Reducing the Risk of Supply Chain Disruptions*, MIT Mgmt. Rev., Spring 2014, http://sloanreview.mit.edu/article/-reducing-the-risk-of-supply-chain-disruptions/..... 8, 9, 15

Dako, Autostainer Link 48, http://www.dako.com/us/ar48/psg38717000/baseproducts.htm 13

Dako, *Dako Autostainer Plus User Guide*, http://www.dako.com/us/0003107_rev_d_man_user_guide_autostainer_plus_english.pdf 13

Dako, *2015 Catalog: Products and Services (Pathology)*, http://www.dako.com/us/-2015-pathology-catalog-dako-us.pdf?-from=catalog-path-2015-us_pdf..... 13

Miscellaneous—Continued:

Dako, ER/PR pharmDx Kit for the Dako Autostainer (K4071), http://www.dako.com/us/download.pdf?objectid=117052002 13

Dako, ER/PR pharmDx Kit (Link) (SK310), http://www.dako.com/us/download.pdf?objectid=117180004 ..... 13, 14

Dako, Safety Data Sheet: Wash Buffer 10x, http://www.dako.com/us/download.pdf?objectid=126645001 14

Dako, Wash Buffer 10x (S3006) Product Specification Sheet, http://www.dako.com/us/download.pdf?objectid=107011002 14

Claudia H. Deutsch, *Supply Chain Software: An Industry on a Thrill Ride,* N.Y. Times, May 31, 1998..... 7

Thomas Ebel et al., *Building New Strengths in the Healthcare Supply Chain,* McKinsey & Co., Jan. 2013, http://www.mckinsey.com/insights/health_systems_and_services/strengthening_health_cares_supply_chain_a_five_step_plan. 8

Edward Feitzinger & Hau L. Lee, *Mass Customization at Hewlett-Packard: The Power of Postponement,* Harvard Bus. Rev., Jan. 1997 10

Miscellaneous—Continued:

Kinaxis, *Comprehensive Supply Chain Visibility Across a Multi-Enterprise Supply Chain*, http://www.kinaxis.com/-Global/resources/case-studies/-comprehensive-supply-chain-visibility-agilent-case-study-kinaxis.pdf 10, 11

Tim Laseter & Keith Oliver, *When Will Supply Chain Management Grow Up?*, strategy+business, Fall 2003, http://www.strategy-business.com/-article/03304?gko=54182 ..... 6, 7

Hau L. Lee, *The Triple-A Supply Chain*, Harvard Bus. Rev., Oct. 2004 ..... 7, 10

James Manyika et al., *Manufacturing the Future: The Next Era of Global Growth and Innovation*, McKinsey & Co., Nov. 2012, http://www.nist.gov/mep/data/-upload/Manufacturing-the-Future.pdf. 6

Mass. Inst. of Technology, MIT Supply Chain Management, http://scm.mit.edu/-program 7

Michigan State Univ. Eli Broad School of Business, Department of Supply Chain Management, https://supplychain.broad-.msu.edu/ 7

Pennsylvania State Univ. Smeal College of Business, Master of Professional Studies in Supply Chain Management, http://www.smeal.psu.edu/mps. 7

Miscellaneous—Continued:

Maria Jesús Sáenz & Elena Revilla, *Creating More Resilient Supply Chains*, MIT Mgmt. Rev., Summer 2014, http://sloanreview.mit.edu/article/creating-more-resilient-supply-chains/ 9

David Simchi-Levi et al., *From Superstorms to Factory Fires: Managing Unpredictable Supply-Chain Disruptions*, Harvard Bus. Rev., Jan. 1, 2014 7

U.S. Food and Drug Administration, *Strategic Plan for Preventing and Mitigating Drug Shortages* (Oct. 2013), http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf 11

INTEREST OF AMICUS CURIAE

Agilent Technologies, Inc. ("Agilent")[1] is a $4 billion publicly-traded U.S. company with 12,000 employees.[2] Its worldwide manufacturing operations stand to be adversely impacted by the decision of the U.S. Court of Appeals for the Federal Circuit in *Promega Corp. v. Life Technologies Corp.*, 773 F.3d 1338 (Fed. Cir. 2014). The Federal Circuit's decision makes U.S.-based manufacturers a target for patent infringement allegations by exposing them to infringement liability for activities and sales occurring outside the U.S. based on a nominal or *de minimis* connection to the U.S. It thereby encourages companies to relocate or prioritize their manufacturing to other countries.

Agilent has a distinguished pedigree in technology and innovation. Originally part of Hewlett-Packard,

---

[1] All parties have been given appropriate notice and consented to the filing of this brief in letters that are on file with the Clerk. Petitioners have filed a blanket consent and the consent of Respondent is being lodged herewith. Pursuant to S. Ct. R. 37.6, counsel for *Amicus* state that no counsel for a party authored this brief in whole or in part and no person or entity, other than *Amicus* or its counsel, made a monetary contribution to the preparation or submission of this brief.

[2] *See* Agilent, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 (Dec. 22, 2014), Sec. & Exch. Comm'n File No. 001-15405 (hereafter, "Agilent 2014 10-K") at p. 3; *See also* Agilent, Agilent Fact Sheet (Mar. 18. 2015). http://www.agilent.com/about/companyinfo/agilent-fact-sheet.pdf. (hereafter, "Agilent Fact Sheet") (clarifying financials after spinoff of measurement business, now Keysight Technologies, Inc.).

it was spun off as a separate company in 1999.[3] It is a leader in developing products and services for life sciences, diagnostics and chemical testing industries.[4] Agilent's products and services help diagnose and research disease, assess petrochemical products, evaluate environmental contamination, detect impurities in materials used in electronics manufacturing, and ensure food safety. [5]

Agilent is a U.S. company, incorporated in Delaware and headquartered in California, but with global manufacturing and sales, and global revenue and workforce. [6] Agilent's revenue is generated 34% in the Americas, 33% in Europe, and 33% in the Asia-Pacific region. Its 12,000-person workforce is located 35% in the Americas, 29% in Europe, and 36% in the Asia Pacific region.[7]

Agilent's life sciences and diagnostic business has manufacturing facilities in California, Colorado and North Carolina in the U.S. Outside of the U.S., Agilent has life sciences manufacturing facilities in Germany, Malaysia, Poland, Singapore and the U.K. Its FDA-registered sites include Texas, Denmark and California. [8]

Agilent's chemical analysis business is similarly diverse and global. Agilent's chemical analysis business has manufacturing facilities in California,

---

[3] *See* Agilent, Company Information, http://www.agilent.com/about/companyinfo/index.html.

[4] *See* Agilent 2014 10-K at pp. 3-4, 8.

[5] *See id.* at pp. 3-4, 8.

[6] *See id.* at pp. 3-4.

[7] *See* Agilent Fact Sheet.

[8] *See* Agilent 2014 10-K at p. 8.

Delaware, and Connecticut in the U.S. Outside of the U.S., it has manufacturing facilities in Australia, Canada, China, Italy, Malaysia, Netherlands, Japan, and the United Kingdom. [9]

As is typical of global advanced technology companies, Agilent manufactures some standard products and also makes highly configurable products. [10] In addition, many of its products incorporate individual components that are used in multiple other Agilent products. It utilizes just-in-time manufacturing and does not maintain a high level of inventory. [11] Accordingly, Agilent must employ advanced global supply chain management systems that are flexible and responsive.

SUMMARY OF ARGUMENT

This case is of compelling interest to Agilent. It is essential for U.S. manufacturers with global operations to have the ability to manufacture components in the U.S. without facing disproportionate liability or undue legal complexity or uncertainty. The decision of the U.S. Court of Appeals for the Federal Circuit increases the potential for and scope of patent infringement liability in a way inconsistent with the statutory language and which was not, and could not have been, contemplated by Congress. Agilent therefore submits this brief, as a Friend of the Court, in support of the Petition of Life Technologies, Inc. requesting that this Court grant *certiorari* to review the decision of the U.S. Court of Appeals for the

---

[9] *See* Agilent 2014 10-K at p. 10.

[10] *See id.* at pp. 8, 10.

[11] *See id.* at pp. 8, 10.

Federal Circuit in *Promega Corp. v. Life Technologies Corp.*, 773 F.3d 1338 (Fed. Cir. 2014).

On review, this Court should reject the Federal Circuit's interpretation as inconsistent with the plain text and purpose of 35 U.S.C. 271(f). The incorporation of commonplace elements manufactured in the U.S. into products that are finished in other countries should not trigger exposure to U.S. patent liability for the value of the finished product other than under the specific, limited circumstances addressed by the plain language of the statute. Further, manufacturers must have the ability to choose the most efficient country for manufacturing of components, rapidly shift supply from one country to another, and rely on backup supply sources, and the Federal Circuit's decision interferes with those essential aspects of modern global supply logistics. For example, except in specific, limited circumstances, manufacturers should not be burdened with performing complex legal analysis of patent exposure with every shift in sourcing or delivery of standard, commonplace components. Under the Federal Circuit's decision, the potential for broad patent liability would need to be considered at the outset in planning the sourcing of even staple, commodity components that are likely to be used in products manufactured or assembled anywhere in the world and the Federal Circuit's interpretation of 271(f) would be a thumb on the scale in favor of foreign manufacturing, even though the quality and cost of U.S. manufacturing is competitive.

ARGUMENT

I. COMPLEX GLOBAL MANUFACTURING OPERATIONS AND SOPHISTICATED SUPPLY CHAIN MANAGEMENT SYSTEMS ARE THE NORM TODAY

Manufacturing has changed profoundly in the 30 years since § 271(f) was enacted. Modern supply chain management requires efficient, flexible, responsive and resilient manufacturing operations that minimize inventory and cost, while allowing for extremely rapid response to changes in customer demand or to crises that disrupt operations. To be competitive, companies must design rapidly adaptable products, and be able to rapidly adapt individual manufacturing sites. This is accomplished through modern supply chain management systems, in which each manufacturing site must be a completely integrated component of the company's operations. The short timeframes for response as part of this organization-wide system do not allow for complex legal analysis of patent liability exposure before each change, especially where that potential liability is based on common, staple components that do not themselves trigger liability.

In contrast, in regulated industries, such as diagnostics, it can be difficult, expensive, and inefficient to move manufacturing to a different facility or country. Once approved manufacturing processes and practices are established at a particular facility or set of facilities (*e.g.*, for multicomponent products), that manufacturing tends to stay where it is absent emergency or other extenuating circumstances. The decision on where to locate long-term manufacturing of regulated products and their components must take into account, among

other things, appropriate respect for the patent rights of others, as must any decision to relocate manufacturing in extenuating circumstances.[12]

In both of the foregoing situations, a rule that imposes outsized liability for global sales of finished products based on shipment of commonplace, but essential, components from the U.S. reduces flexibility, increases the risk and cost of U.S. manufacturing, and will discourage companies from manufacturing in the U.S.

A. Origins and Evolution of Supply Chain Management Systems

Although the concept may seem intuitive today, the term "supply chain management" was only coined by the management consultant Keith Oliver in 1982, two years before § 271(f) was enacted.[13] At that time, it was radical to suggest that a company's production, sales, finance, marketing and distribution functions should work in a coordinated fashion, to eliminate problems arising from each function viewing its goals and plans in isolation, and to instead view these functions as part of an integrated supply chain in order to make finished goods available more efficiently.[14]

Today, supply chain management is a well-established field, with academic programs at the

---

[12] *See* James Manyika et al., *Manufacturing the Future: The Next Era of Global Growth and Innovation*, McKinsey & Co., Nov. 2012, at p. 54, http://www.nist.gov/mep/data/-upload/Manufacturing-the-Future.pdf.

[13] *See* Tim Laseter & Keith Oliver, *When Will Supply Chain Management Grow Up?*, strategy+business, Fall 2003, http://www.strategy-business.com/article/03304?gko=54182.

[14] *See id.*

Massachusetts Institute of Technology,[15] Michigan State University,[16] and Penn State,[17] among many others. Companies have chief procurement officers to lead these efforts. [18] Specialized software is employed to design and monitor the supply chain.[19] Supply chain management systems are ever more sophisticated in their efforts to analyze the entire supply chain strategically to balance cost, risk, and flexibility.[20] There is a greater understanding and sophistication of these tradeoffs, as high-speed, low-cost supply chains proved unable to respond to unexpected changes in supply.[21] There is constant attention to designing supply chains that have sufficient flexibility and redundancy to be resilient in the face of political unrest and natural disasters.[22] Modern supply chain management practices did not arise from any desire to thwart or avoid liability under U.S. patent law. See *Deepsouth Packing Co. v.*

---

[15] Mass. Inst. of Technology, MIT Supply Chain Management, http://scm.mit.edu/program.

[16] Michigan State Univ. Eli Broad School of Business, Department of Supply Chain Management, https://supplychain.broad.msu.edu/.

[17] Penn. State Univ. Smeal College of Business, Master of Professional Studies in Supply Chain Management, http://www.smeal.psu.edu/mps.

[18] *See* Laseter & Oliver, *supra* n.13.

[19] *See* Claudia H. Deutsch, *Supply Chain Software: An Industry on a Thrill Ride,* N.Y. Times, May 31, 1998.

[20] *See* Laseter & Oliver, *supra* n.13.

[21] *See* Hau L. Lee, *The Triple-A Supply Chain,* Harvard Bus. Rev., Oct. 2004.

[22] *See* David Simchi-Levi et al., *From Superstorms to Factory Fires: Managing Unpredictable Supply-Chain Disruptions,* Harvard Bus. Rev., Jan. 1, 2014.

Laitram Corp., 406 U.S. 518, 520 n. 5 (1972) ("Deepsouth is entirely straightforward in indicating that its course of conduct is motivated by a desire to avoid patent infringement").

B. Modern Supply Chain Management Requires Agile, Resilient, Efficient Systems for Supplying Products and Components Worldwide

Supply chain management must be capable of dealing with ordinary recurring risks, such as labor disputes, transportation breakdowns, and changes in customer preference, and extremely rare but devastating disruptions.[23]

A recent experience of Cisco Systems, Inc. ("Cisco") is illustrative of the level of responsiveness that is expected in today's business environment. After Hurricane Katrina, Cisco found that its supply chain management was inadequate to deal with the immediate demand for $1 billion in new equipment to replace damaged telecommunications infrastructure. Cisco's risk mitigation and response system could not locate all its products in the supply chain or understand the financial impacts of emergency sales. In response to this failure, Cisco redesigned its supply chain management. As a result, six years later, after the March 11, 2011 Japanese earthquake and tsunami, Cisco was able within 12 hours to assess the impact on 300 suppliers in the region and

---

[23] *See* Sunil Chopra & Manhohan S. Sodhi, *Reducing the Risk of Supply Chain Disruptions*, MIT Mgmt. Rev., Spring 2014, at 73, 74, http://sloanreview.mit.edu/article/reducing-the-risk-of-supply-chain-disruptions/.

7,000 affected parts, plan a response, and identify teams to field customer inquiries. [24]

This current emphasis on adaptability and resilience represents a shift from previous decades, when manufacturers focused more narrowly on minimizing inventory and trimming costs of production. Some of the techniques used to lower production cost — such as outsourcing to low-cost production sites in faraway countries, relying on fewer suppliers, and excessively relying on common interchangeable parts — were rejected in favor of truly modern supply chain systems that balanced many factors.[25]

C. Agilent's Supply Chain Management Illustrates the Challenges Faced by Multinational Manufacturers

Agilent is in many ways typical of modern supply chain management trends for advanced technology global companies. Its market is global, drawn equally from Europe, Asia and the Americas, and Agilent deploys its workforce and manufacturing operations among those regions as well. It faces routine fluctuations in demand as well as the risk of major unexpected disruptions.

Like its peers, Agilent relies upon extremely sophisticated supply chain management consulting and tools to manage the variation in demand for its

---

[24] *See* Maria Jesús Sáenz & Elena Revilla, *Creating More Resilient Supply Chains*, MIT Mgmt. Rev., Summer 2014, http://sloanreview.mit.edu/article/creating-more-resilient-supply-chains/.

[25] *See* Chopra & Sodhi, *supra* n.23, at 74.

products.[26] One notable distinction from a consumer goods manufacturer is that much of Agilent's market is "high mix-low volume" — that is, it moves a comparatively small number of units, and clients demand a much greater degree of customization. [27] And, of course, its products are more complex and subject to patent coverage than simple consumer goods like t-shirts and scarves.

Agilent has responded by designing products that use common components that can be readily customized in different configurations in response to demand. This process is termed "postponement" because it allows companies to maintain the ability to respond to market demand later in the production cycle.[28] Indeed, Hewlett-Packard, from which Agilent was spun off in 1999, was a pioneer in successfully using modular product design to "mass-customize" products quickly while keeping its costs low.[29] In addition, like its peers, Agilent manages risk by establishing multiple sources of supply and redesigning products to use alternative components.[30]

---

[26] *See* Kinaxis, *Comprehensive Supply Chain Visibility Across a Multi-Enterprise Supply Chain*, http://www.kinaxis.com/Global/resources/case-studies/comprehensive-supply-chain-visibility-agilent-case-study-kinaxis.pdf (hereafter, "Kinaxis Study"). (While this study was prepared prior to the spinoff of Keysight from Agilent in 2014, the case study remains accurate for the facts cited in this *amicus* brief.)

[27] *See* Kinaxis Study.

[28] *See* Hau L. Lee, *supra* n.21.

[29] Edward Feitzinger & Hau L. Lee, *Mass Customization at Hewlett-Packard: The Power of Postponement*, Harvard Bus. Rev., Jan. 1997.

[30] *See* Agilent 2014 10-K at p. 15.

Agilent must be able to plan, instantly monitor and tightly manage a supply chain network that involves participants scattered around the globe. [31]

In diagnostic, pathology and life sciences businesses, shortages have additional consequences of greater public concern. Shortages in the health care industry make manufactures, consumers, and patients vulnerable to counterfeiters and gray market vendors selling healthcare products at a significant markup, which poses risks to patients as well as the corporate bottom line.[32] This can result in ineffective therapy, increased drug resistance due to substandard medications, and injury from counterfeit substances.[33] Shortages can delay treatment, cause physicians to choose therapies that are less effective or have avoidable risks, and disrupt clinical trials and other research.[34] In addition, the potential for patent infringement liability for the value of finished healthcare products that are assembled and sold outside the U.S. using common, staple components sourced from the U.S. would tend to make U.S. manufacturing of such components less desirable.

---

[31] *See* Kinaxis Study.

[32] *See* Thomas Ebel et al., *Building New Strengths in the Healthcare Supply Chain*, McKinsey & Co., Jan. 2013, at 3, http://www.mckinsey.com/insights/health_systems_and_services/strengthening_health_cares_supply_chain_a_five_step_plan.

[33] *See id.* at 4.

[34] *See* U.S. Food and Drug Administration, *Strategic Plan for Preventing and Mitigating Drug Shortages* (Oct. 2013) at 8, http://www.fda.gov/downloads/-Drugs/DrugSafety/DrugShortages/UCM372566.pdf.

II. AGILENT'S ESTROGEN/PROGESTERONE RECEPTIVITY TEST KITS FOR BREAST CANCER DIAGNOSIS ILLUSTRATE THE POTENTIAL UNDUE CONSEQUENCES OF THE FEDERAL CIRCUIT'S RULING

Reviewing a single Agilent product that includes several components used in other Agilent products may help illustrate the scope of the problem created by the Federal Circuit's broad interpretation of the statute.

A. Estrogen/Progesterone Receptor Test Kits for Breast Cancer Diagnosis Illustrate the Use of Commonplace Components

In the diagnosis of breast cancer, testing for various molecular factors is now routine to help assess the aggressiveness of the cancer and identify factors that may fuel tumor growth or be responsive to treatment. Receptivity to estrogen and progesterone is one of these factors, and testing of tumor samples for estrogen-progesterone responsiveness ("ER/PR") is standard of care.[35] Patients whose tumors are strongly ER/PR receptive can make lifestyle changes (such as avoiding hormonal methods of birth control, pregnancy, and estrogen replacement therapy for menopause) and are treated with medications that alter the body's production and response to these hormones.[36]

---

[35] American Society of Clinical Oncology, *Estrogen and Progesterone Receptor Testing for Breast Cancer,* http://www.cancer.net/research-and-advocacy/asco-care-and-treatment-recommendations-patients/estrogen-and-progesterone-receptor-testing-breast-cancer.

[36] *See id.*

Agilent offers several ER/PR kits and products, which are described in the pathology catalogue of Agilent's Dako subsidiary.[37] One of these products is product number SK310, an ER/PR test kit, which is designed for use in a testing platform known as Automated Link.[38] A similar ER/PR test designed for use in a Dako Autostainer is K4071. [39] Automated Link and Autostainer are instruments that allow tissue samples to be processed more rapidly.[40] Agilent also sells the ER and PR antibodies separately.[41]

The SK310 ER/PR kit product specification lists the kit components.[42] These include epitope retrieval solution (a citrate buffer with an antimicrobial agent); peroxidase-blocking reagent; ER antibody cocktail; PR antibody; negative control reagent; visualization reagent; DAB+ substrate buffer; DAB+ chromogen; reagent bottles; wash buffer concentrate;

---

[37] Dako, *2015 Catalog: Products and Services (Pathology)*, pp. 150-151, http://www.dako.com/us/2015-pathology-catalog-dako-us.pdf?from=catalog-path-2015-us_pdf (hereafter, "Pathology Catalog"). Dako was acquired by Agilent in 2012. *See* Agilent 2014 10-K at 3.

[38] *See id.* at pp. 46, 150.

[39] *See id.* at pp. 58, 150; Dako, ER/PR pharmDx Kit for the Dako Autostainer (K4071), http://www.dako.com/us/download.pdf?objectid=117052002.

[40] *See* Dako, *Dako Autostainer Plus User Guide*, http://www.dako.com/us/0003107_rev_d_man_user_guide_autostainer_plus_english.pdf; Dako, Autostainer Link 48, http://www.dako.com/us/ar48/psg38717000/baseproducts.htm.

[41] *See* Pathology Catalog, at p. 67.

[42] *See* Dako, ER/PR pharmDx Kit (Link) (SK310), http://www.dako.com/us/download.pdf?objectid=117180004 (hereafter, SK310 Product Specifications).

and control slides.[43] Additional materials and equipment, such as slides, coverslips, water, a microscope, a pressure cooker, and tissue samples, are required, but not supplied with the kit.[44]

One of the components of the SK310 kit, wash buffer concentrate, is used to prepare a wash buffer for use in immunohistochemical testing procedures, which use antibodies to identify specific protein components of tissue samples.[45] The wash buffer can be used in Dako testing equipment or when staining manually.[46] This particular wash buffer concentrate is included in seven Agilent products, including both ER/PR test kits, and other test kits, and is sold separately.[47]

The wash buffer is essential to the test. It is used to remove unwanted molecules, but is relatively inert so that it does not react with and alter the specimen.[48] While it is important for a wash buffer to be formulated correctly to avoid generating false negative or positive results, wash buffer is a commonplace component in many tissue testing procedures and finished products.

---

[43] *See* SK310 Product Specifications at pp. 1-3.

[44] *See id.* at p. 3.

[45] Dako, Wash Buffer 10x (S3006) Product Specification Sheet, p. 1, http://www.dako.com/us/download.pdf?objectid=107011002

[46] *See id.*

[47] Dako, Safety Data Sheet: Wash Buffer 10x, http://www.dako.com/us/download.pdf?objectid=126645001 (Listing products in which the wash buffer is used, under "material uses.").

[48] *See* SK310 Product Specifications, at p. 8 (general limitations no. 7), p. 10 ("Troubleshooting").

B. The Federal Circuit's Interpretation Could Render the Manufacturing and Use of Common, Interchangeable Components in Tests Kits Such as the Estrogen/Progesterone Receptor Kits Unduly Complex

Technology-based products, such as tests for serious diseases such as breast cancer, have the potential to give rise to intellectual property disputes. *See, e.g., Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013). The risk of such disputes must be considered by companies like Agilent in designing business processes and in making major decisions, such as where to locate manufacturing operations.

The use of common components has for decades been a common way for companies like Agilent to achieve cost efficiencies.[49] As discussed above, Agilent maintains sales and manufacturing operations around the globe, using modern supply chain management systems.

The Federal Circuit's decision suggests that if Agilent makes a component like the wash buffer in the U.S., it potentially subjects itself to a jurisdictional hook triggering U.S. patent liability for all products manufactured outside the U.S. in which the wash buffer is used. Likewise, if the wash buffer is manufactured in several locations, shifting supply to the U.S. in response to a need elsewhere could trigger U.S. patent liability. This is a serious concern to companies like Agilent that would like to locate manufacturing where it makes sense from an operational standpoint, while also respecting the legitimate patent rights of others.

---

[49] *See* Chopra & Sodhi, *supra* n.23, at 77.

III. THE FEDERAL CIRCUIT'S DECISION INCREASES THE RISK AND COST OF U.S. MANUFACTURING OF COMPONENTS AND THEREBY DISCOURAGES U.S. MANUFACTURING

Section 271(f) was enacted to "close a loophole" in response to this Court's decision in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972). *See* 1984 U.S. Code Cong. & Admin. News, p. 5827, *Section-By-Section Analysis of H.R. 6286, Patent Law Amendments Act of 1984*, 130 Cong. Rec. H 10525 (Oct. 1, 1984).

It is one thing to tell U.S. manufacturers that they cannot avoid global patent liability by inducing their customers to assemble overseas a product that consists of a "substantial portion" of U.S.-made components. Such technical workarounds would previously have allowed manufacturers to adhere to the strict letter, but in Congress's view, not the spirit of the law.

It is quite another thing to say that inclusion of any "necessary" component manufactured in the U.S. is a jurisdictional hook that potentially triggers U.S. patent liability. U.S. manufacturing can be desirable, thanks to its speed, quality, and proximity to U.S. customers. But the Federal Circuit's message to U.S. manufacturers, especially in industries in which patent liability is a prevalent concern, is to not use U.S.-made components unless absolutely necessary.

The Federal Circuit's decision also discourages companies from constructing and investing in their own manufacturing infrastructure in the U.S. Modern supply chain management requires companies to have the capacity to rapidly shift production and products worldwide in response to

change. Many U.S. companies can ill afford the time or resources to undertake a comprehensive component-by-component patent risk analysis when making decisions to source components from one location versus another, especially where the analysis is complex, potentially ambiguous, and relates to individual components that are common, staple, and would not themselves invoke patent liability. One solution to the problem presented by the Federal Circuit's interpretation would be to isolate U.S. manufactured components for use only in products that will be finished and sold in the U.S. But that is inconsistent with the realities of modern manufacturing — the fundamental point of modern supply chain management is to promote efficiency, reduce cost, and facilitate rapid deployment of materials, components and products, globally.

In the wake of the Federal Circuit's decision, manufacturers will now need to take an increased level of exposure for global sales into consideration in their evaluation of the risks associated with their manufacturing operations. This increased liability will place a thumb on the scale in favor of foreign manufacturing, which is not what the statutory text requires, and not what Congress intended when enacting the statue.

CONCLUSION

This Court should grant the Petition for Certiorari, and review the decision of the Federal Circuit, for the reasons explained above and by Petitioners.

Respectfully submitted.

Bradford Paul Schmidt
AGILENT TECHNOLOGIES, INC.
5301 Stevens Creek Boulevard
Santa Clara, CA 95051

John M. Griem, Jr.*
Judith M. Wallace
CARTER LEDYARD & MILBURN LLP
2 Wall Street
New York, NY 10005
(212) 732-3200
griem@clm.com

Counsel for Amicus Curiae
* Counsel of Record

July 28, 2015